**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Appellants:
DAVID E. BERG, ET AL.

Serial No.:
10/694,033

Atty. Docket No.:
4425-PA1C2

Examiner: FORD, ALLISON M.

Art Unit: 1651

Filed:
25 October 2001

For:
METHOD FOR DETECTING, TREATING, AND MONITORING CONDITIONS ASSOCIATED WITH ACTIVATION OF THE COAGULATION RESPONSE

**BRIEF FOR APPELLANTS**
**(37 C.F.R. 41.37)**

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SIR:

Please consider the contents of the following Brief for Appellants.

## I. REAL PARTY IN INTEREST

All of the right, title and interest in and to the above-described Patent Application are owned by Appellants David E. Berg, Lois Hill Berg, and Harold H. Harrison, who are the real parties in interest.

## II. RELATED APPEALS AND INTERFERENCES

There are no other appeals, interferences, or judicial proceedings known to Appellants, the Appellants's legal representative, or assignee which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

## III. STATUS OF THE CLAIMS

1. Claims 1-69 are canceled. Claims 70-87 are new. Claims 70, 71, 72, 77, 78, and 84-87 were amended in the response dated 9 February 2007. Claims 70, 77, 84, and 86 are independent claims. Claims 71-76 depend from independent claim 70. Claims 78-83 depend from independent claim 77. Claim 85 depends from independent claim 84. Claim 87 depends from independent claim 86. Claims 70-87 are pending in this case, and are the claims subject to this appeal.

2. A copy of claims 70-87, the claims on appeal, is provided in Claims Appendix A.

3. Claims 70-72, 74-79, and 81-87 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Wintrobe et al.

4. Claims 70-87 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Sorensen et al.

5. Claims 70-87 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Dati et al.

6. Claims 77-83 are deemed substantial duplicates of claims 70-76.

7. Claim 84 is deemed a substantial duplicate of claims 74 and 81.

8. Claim 86 is deemed a substantial duplicate of claims 76 and 83.

9. Claims 70-87 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 45-63 of copending Application No. 10/915,018.

## IV. STATUS OF AMENDMENTS FILED SUBSEQUENT TO FINAL REJECTION

No response to the final rejection mailed 18 May 2007, Paper No. 20070426, was mailed and no amendments to the specification or claims were proposed.

## V. SUMMARY OF CLAIMED SUBJECT MATTER

Independent Claim 70

The subject matter claimed in independent claim 70, on appeal, is an ex vivo diagnostic method including identifying conditions that each cause a low level activation of the coagulation response in blood (page 1 lines 18-23 of the specification; page 5 lines 4-15 of the specification; page 11 lines 3-14 of the specification; page 12, lines 3-10 of the specification), providing a blood sample taken from a subject (page 7 lines 8-9 of the specification), and providing different blood tests that are each for identifying low level activation of the coagulation response in blood (page 6 lines 17-22 of the specification). The method in claim 70 next specifies performing each of the different blood tests on the blood sample (page 7 lines 7-16 of the specification), and if at least two of the different blood tests identify low level activation of the coagulation response in the blood sample are abnormal, using the at least two of the blood tests to assist in diagnosing the subject with one of the conditions (page 2 lines 4-9 of the specification; page 6 line 17 of the specification to page 7 line 16 of the specification).

Independent Claim 77

The subject matter claimed in independent claim 77, on appeal, is an ex vivo diagnostic method including identifying a condition that causes low level activation of the coagulation response in blood (page 1 lines 18-23 of the specification; page 5 lines 4-15 of the specification; page 11 lines 3-14 of the specification; page 12, lines 3-10 of the specification), providing a blood sample taken from a subject (page 7 lines 8-9 of the specification), and providing different blood tests that are each for identifying low level activation of the coagulation response in blood (page 6 lines 17-22 of the specification). The method of claim 77 further specifies performing the different blood tests on the blood sample (page 7 lines 7-16 of the specification), and if at least two of the different blood tests identify low level activation of the coagulation response in the blood sample, using the at least two of the blood tests to assist in diagnosing the subject with the condition (page 2 lines 4-9 of the specification; page 6 line 17 of the specification to page 7 line 16 of the specification).

Independent Claim 84

The subject matter claimed in independent claim 84, on appeal, is an ex vivo diagnostic method including identifying conditions that each cause a low level activation of the coagulation response in blood (page 1 lines 18-23 of the specification; page 5 lines 4-15 of the specification; page 11 lines 3-14 of the specification; page 12, lines 3-10 of the specification), providing a blood sample taken from a subject (page 7 lines 8-9 of the specification), and providing different blood tests that are each for identifying low level activation of the coagulation response in blood (page 6 lines 17-22 of the specification). According to claim 84 the blood tests comprise tests for at least two of fibrinogen, prothrombin fragment 1+2, thrombin/antithrombin complexes, soluble fibrin monomer, and platelet activation (page 2 lines 6-9 of the specification, page 6 lines 17-22 of the specification). The method of claim 84 next specifies obtaining a result for each of the blood tests, observing the results, and if at least two of the results are abnormal, using the abnormal results to assist in diagnosing the subject with one of the conditions (page 2 lines 4-9 of the specification; page 6 line 17 of the specification to page 8 line 14 of the specification).

Independent Claim 86

The subject matter claimed in independent claim 86, on appeal, is an ex vivo diagnostic method including identifying a condition that causes a low level activation of the coagulation response in blood (page 1 lines 18-23 of the specification; page 5 lines 4-15 of the specification; page 11 lines 3-14 of the specification; page 12, lines 3-10 of the specification), providing a blood sample taken from a subject (page 7 lines 8-9 of the specification), and providing different blood tests that are each for identifying low level activation of the coagulation response in blood (page 6 lines 17-22 of the specification). The blood tests according to claim 86 comprise tests for fibrinogen, prothrombin fragment 1+2, thrombin/antithrombin complexes, soluble fibrin monomer, and platelet activation (page 6 lines 17-22 of the specification). According to claim 86, if at least two of the results are abnormal, the method next specifies using the abnormal results to assist in diagnosing the subject with the condition (page 2 lines 4-9 of the specification; page 6 line 17 of the specification to page 8 line 14 of the specification).

## VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Claims 70-72, 74-79, and 81-87 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Wintrobe et al. The first issue to be resolved in this appeal is, therefore, whether claims 70-72, 74-79, and 81-87 are patentable over Wintrobe et al.

2. Claims 70-87 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Sorensen et al. The second issue to be resolved in this appeal is, therefore, whether claims 70-87 are patentable over Sorensen et al.

3. Claims 70-87 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Dati et al. The third issue to be resolved in this appeal is, therefore, whether claims 70-87 are patentable over Dati et al.

4. Claims 77-83 are deemed substantial duplicates of claims 70-76. The fourth issue to be resolved in this appeal is, therefore, whether claims 77-83 are substantial duplicates of claims 70-76.

5. Claim 84 is deemed a substantial duplicate of claims 74 and 81. The fifth issue to be resolved in this appeal is, therefore, whether claim 84 is a substantial duplicate of claims 74 and 81.

6. Claim 86 is deemed a substantial duplicate of claims 76 and 83. The sixth issue to be resolved in this appeal is, therefore, whether claim 86 is a substantial duplicate of claims 76 and 83.

7. Claims 70-87 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 45-63 of copending Application No. 10/915,018. The seventh issue to be resolved in this appeal is, therefore, whether claims 70-87 unpatentable over claims 45-63 of copending Application No. 10/915,018.

## VII. ARGUMENT

**A.**

**Issue**: Whether claims 70-72, 74-79, and 81-87 are patentable over Wintrobe et al.

Claims 70-72, 74-79, and 81-87 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Wintrobe et al. Appellants respectfully traverse this rejection. The claims are presented in one group by the examiner, that group of claims now on appeal being claims 70-72, 74-79, and 81-87. None of the claims necessarily stands or falls together. Accordingly, independent claims 70, 77, 84, and 86 are treated below individually, as are the corresponding claims depending from each of the independent claims.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. V. Union Oil Co. of California*, 2 USPQ2d 1051, 1053, (Fed. Cir. 1987). Also, "[a]ll words in a claim must be considered in judging patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 165 USPQ 494. 496 (CCPA 1970).

Furthermore, section 102 is designed to specifically exclude from patentable subject matter anything this is considered old. To successfully combat a prima facie case of anticipation, the Applicant must show that not all elements of prima facie anticipation have been met. The Federal Circuit endorsed this view in *In re Oetiker*, 977 F.2d 1443, 24 USPQ 2d 1443 at 1444 (Fed. Cir. 1992) stating "[i]f the examination at the initial stage does not produce a prima facie case of unpatentability, then without more the Applicant is entitled to grant of the patent."

Wintrobe et al. disclose laboratory methods for the study of hemostasis, e.g., the stoppage of bleeding, and blood coagulation and blood clotting defects. On page 1053, Wintrobe et al. discuss platelet functions and platelet adhesiveness. On page 1060, Wintrobe et al. discuss methods for the quantitative assay of plasma fibrinogen as an example of a test of the coagulation phase. On pages 1060-1061, Wintrobe et al. discuss tests for intravascular coagulation and fibrinolysis, e.g., the enzymatic breakdown of fibrin. On page 1062, Wintrobe et al. discuss Table 33-3, which summarizes tests that may be carried out on bleeding patients for the purpose of determining coagulation defects that bleeding patients may have.

Independent claim 70

Claim 70 claims an ex vivo diagnostic method including identifying conditions that each cause a low level activation of the coagulation response in blood; providing a blood sample taken from a subject; providing different blood tests that are each for identifying low level activation of the coagulation response in blood; performing each of the different blood tests on the blood sample; and if at least two of the different blood tests identify low level activation of the coagulation response in the blood sample are abnormal, using the at least two of the blood tests to assist in diagnosing the subject with one of the conditions.

Wintrobe et al. are concerned with the study of hemostasis, e.g., the stoppage of bleeding, and blood coagulation and blood clotting defects. In Appellants' claim 70, the method is not directed to stopping bleeding, the study or science of blood coagulation, or tests merely for determining coagulation abnormalities that bleeding patients may have. Quite to the contrary, Appellants' method set forth in claim 70 is concerned first with identifying conditions that each cause a low level activation of the coagulation response in blood, performing tests on the blood sample that are each for identifying low

level activation of the coagulation response in blood, and if at least two of the different blood tests identify low level activation of the coagulation response in the blood sample are abnormal, using the at least two of the blood tests to assist in diagnosing the subject with one of the conditions. The ability to test a blood sample according to claim 70 in order to determine whether the blood sample has low level activation of the coagulation response provides a way to assist in diagnosing the subject from which the sample was taken with a condition that causes a low level activation of the coagulation response. Using the result of the method of claim 70 to assist in the diagnosis is a positive claim limitation.

Table 33-3 in Wintrobe et al. identify four tests, e.g., platelet count, bleeding time, partial thromboplastin time, and prothrombin time, which may be used to diagnose blood clotting defects in bleeding patients. The four tests identified in Table 33-3 are not tests for identifying low level activation of the coagulation response in blood, and the results of the four tests, in any combination, are not used, or thus capable of being used, to assist in the diagnosis of a subject from which the blood sample was taken with a condition that causes a low level activation of the coagulation response in blood.

In sum, Wintrobe et al. have no application toward Appellants' claim 70 as Wintrobe et al. altogether fail to identify blood tests that are each for identifying low level activation of the coagulation response in blood, fail to specify performing such tests on a blood sample taken from a subject, and fail to specify if at least two of the different blood tests identify low level activation of the coagulation response in the blood sample are abnormal then using the at least two of the blood tests to assist in diagnosing the subject with one of the conditions that cause a low level activation of the coagulation response in blood, as specified by Appellants in claim 70. Accordingly, Wintrobe et al. do not, and cannot, anticipate Appellants' claim 70.

Dependent claims 71, 72, and 74-76

Claims 71, 72, and 74-76 depend upon claim 70 that is allowable according to the argument set forth above and, therefore, are allowable.

Independent claim 77

Claim 77 specifies an ex vivo diagnostic method including identifying a condition that causes low level activation of the coagulation response in blood; providing a blood sample taken from a subject; providing different blood tests that are each for identifying low level activation of the coagulation response in blood; performing the different blood tests on the blood sample; and if at least two of the different blood tests identify low level activation of the coagulation response in the blood sample, using the at least two of the blood tests to assist in diagnosing the subject with the condition.

As indicated above in connection with claim 70, Wintrobe et al. Wintrobe et al. have no application toward Appellants' claim 77 as Wintrobe et al. altogether fail to identify blood tests that are each for identifying low level activation of the coagulation response in blood, fail to specify performing such tests on a blood sample taken from a subject, and fail to specify if at least two of the different blood tests identify low level activation of the coagulation response in the blood sample are abnormal then using the at least two of the blood tests to assist in diagnosing the subject with one of the conditions that cause a low level activation of the coagulation

response in blood. Accordingly, Wintrobe et al. do not, and cannot, anticipate Appellants' claim 77.

Dependent claims 78, 79, and 81-83

Claims 78, 79, and 81-83 depend upon claim 77 that is allowable according to the argument set forth above and, therefore, are allowable.

Independent claim 84

Claim 84 specifies an ex vivo diagnostic method including identifying conditions that each cause a low level activation of the coagulation response in blood, providing a blood sample taken from a subject; providing different blood tests that are each for identifying low level activation of the coagulation response in blood; the blood tests comprising tests for at least two of fibrinogen, prothrombin fragment 1+2, thrombin/antithrombin complexes, soluble fibrin monomer, and platelet activation; obtaining a result for each of the blood tests; observing the results; and if at least two of the results are abnormal, using the abnormal results to assist in diagnosing the subject with one of the conditions.

As indicated above in connection with claim 70, Wintrobe et al. have no application toward Appellants' claim 84 as Wintrobe et al. altogether fail to identify blood tests that are each for identifying low level activation of the coagulation response in blood, fail to specify performing such tests on a blood sample taken from a subject, and fail to specify if at least two of the different blood tests identify low level activation of the coagulation response in the blood sample are abnormal then using the at least two of the blood tests to assist in diagnosing the subject with one of the conditions that cause a low level activation of the coagulation response in blood. Accordingly, Wintrobe et al. do not, and cannot, anticipate Appellants' claim 84.

Dependent claim 85

Claim 85 depends upon claim 84 that is allowable according to the argument set forth above and, therefore, is allowable.

Independent claim 86

Claim 86 specifies an ex vivo diagnostic method including identifying a condition that causes a low level activation of the coagulation response in blood; providing a blood sample taken from a subject; providing different blood tests that are

each for identifying low level activation of the coagulation response in blood; the blood tests comprising tests for fibrinogen, prothrombin fragment 1+2, thrombin/antithrombin complexes, soluble fibrin monomer, and platelet activation; and if at least two of the results are abnormal, using the abnormal results to assist in diagnosing the subject with the condition.

As indicated above in connection with claim 70, Wintrobe et al. have no application toward Appellants' claim 86 as Wintrobe et al. altogether fail to identify blood tests that are each for identifying low level activation of the coagulation response in blood, fail to specify performing such tests on a blood sample taken from a subject, and fail to specify if at least two of the different blood tests identify low level activation of the coagulation response in the blood sample are abnormal then using the at least two of the blood tests to assist in diagnosing the subject with one of the conditions that cause a low level activation of the coagulation response in blood. Accordingly, Wintrobe et al. do not, and cannot, anticipate Appellants' claim 86.

Dependent claim 87

Claim 87 depends upon claim 86 that is allowable according to the argument set forth above and, therefore, is allowable.

**B.**

**Issue**: Whether claims 70-87 are patentable over Sorensen et al.

Claims 70-87 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Sorensen et al. Appellants respectfully traverse this rejection. The claims are presented in one group by the examiner, that group of claims now on appeal being claims 70-87. None of the claims necessarily stands or falls together. Accordingly, independent claims 70, 77, 84, and 86 are treated below individually, as are the corresponding claims depending from each of the independent claims.

Sorensen et al. teach a study to detect activation of coagulation by measuring prothrombin fragment 1 and 2, thrombin-antithrombin III complex, fibrin degradation products, fibrinogen degradation products, and soluble fibrin monomers in plasma from 39 patients with trauma, namely, fractures of the

lower extremities. The study in Sorensen et al., which is carried out with patients having suffered trauma, found substantial haemostatic activation of coagulation as an immediate response to trauma, and that increased levels of prothrombin fragment 1 and 2, thrombin-antithrombin III complex, fibrin degradation products, fibrinogen degradation products, and soluble fibrin monomers appear to be a normal physiological reaction after fractures of the lower extremities.

Clearly, Sorensen et al. show that a trauma such as a fracture of the lower extremity is a thrombic event that causes substantial haemostatic activation of coagulation in blood as indicated by increased levels of prothrombin fragment 1 and 2, thrombin-antithrombin III complex, fibrin degradation products, fibrinogen degradation products, and soluble fibrin monomers, which are not genetic and metabolic procoagulant factors capable of indicating a hereditary propensity for hypercoagulation in a blood sample. Prothrombin fragment 1 and 2, thrombin-antithrombin III complex, fibrin degradation products, fibrinogen degradation products, and soluble fibrin monomers are activation or result markers increased levels of which are indicated after a trauma thereby indicating a haemostatic

activation of coagulation in blood, namely, evidence of coagulation.

Independent claim 70

Claim 70 claims an ex vivo diagnostic method including identifying conditions that each cause a low level activation of the coagulation response in blood; providing a blood sample taken from a subject; providing different blood tests that are each for identifying low level activation of the coagulation response in blood; performing each of the different blood tests on the blood sample; and if at least two of the different blood tests identify low level activation of the coagulation response in the blood sample are abnormal, using the at least two of the blood tests to assist in diagnosing the subject with one of the conditions.

As explained above, the study in Sorensen et al., which is carried out with patients having suffered trauma, found substantial haemostatic activation of coagulation as an immediate response to trauma, and that increased levels of prothrombin fragment 1 and 2, thrombin-antithrombin III complex, fibrin degradation products, fibrinogen degradation products, and soluble fibrin monomers appear to be a normal physiological

reaction after fractures of the lower extremities. Clearly, the method in Sorensen et al. do not have all of the steps of the invention claimed in claim 70, and is for an entirely different purpose, the results of which indicate the existence of coagulation. Because the method in Sorensen et al. is for an entirely different purpose from the claimed invention set forth in claim 70 and obtains results that are entirely different from Appellants' invention set forth in claim 70, one having ordinary skill in the art in looking at Sorensen et al. would have no way of arriving at Appellants' claimed invention. Thus, any inherency argument must fail. Since Sorensen et al. do not disclose all of the steps of Appellants' method claimed in claim 70, Sorensen et al. cannot function as a section 102 reference against claim 70. Thus, Sorensen et al. do not anticipate claim 70, since each and every element as set forth in the claim is not found, either expressly or inherently described, in Sorensen et al.

In sum, Sorensen et al. altogether fail to identify blood tests that are each for identifying low level activation of the coagulation response in blood, fail to specify performing such tests on a blood sample taken from a subject, and fail to specify if at least two of the different blood tests identify

low level activation of the coagulation response in the blood sample are abnormal then using the at least two of the blood tests to assist in diagnosing the subject with one of the conditions that cause a low level activation of the coagulation response in blood. Accordingly, Sorensen et al. do not, and cannot, anticipate Appellants' claim 70.

Dependent claims 71-76

Claims 71-76 depend upon claim 70 that is allowable according to the argument set forth above and, therefore, are allowable.

Independent claim 77

Claim 77 specifies an ex vivo diagnostic method including identifying a condition that causes low level activation of the coagulation response in blood; providing a blood sample taken from a subject; providing different blood tests that are each for identifying low level activation of the coagulation response in blood; performing the different blood tests on the blood sample; and if at least two of the different blood tests identify low level activation of the coagulation response in the blood sample, using the at least two of the blood tests to assist in diagnosing the subject with the condition.

As indicated above in connection with claim 70, Sorensen et al. altogether fail to identify blood tests that are each for identifying low level activation of the coagulation response in blood, fail to specify performing such tests on a blood sample taken from a subject, and fail to specify if at least two of the different blood tests identify low level activation of the coagulation response in the blood sample are abnormal then using the at least two of the blood tests to assist in diagnosing the subject with one of the conditions that cause a low level activation of the coagulation response in blood. Accordingly, Sorensen et al. do not, and cannot, anticipate Appellants' claim 77.

Dependent claims 78-83

Claims 78-83 depend upon claim 77 that is allowable according to the argument set forth above and, therefore, are allowable.

Independent claim 84

Claim 84 specifies an ex vivo diagnostic method including identifying conditions that each cause a low level activation of the coagulation response in blood, providing a blood sample taken from a subject; providing different blood tests that are

each for identifying low level activation of the coagulation response in blood; the blood tests comprising tests for at least two of fibrinogen, prothrombin fragment 1+2, thrombin/antithrombin complexes, soluble fibrin monomer, and platelet activation; obtaining a result for each of the blood tests; observing the results; and if at least two of the results are abnormal, using the abnormal results to assist in diagnosing the subject with one of the conditions.

As indicated above in connection with claim 70, Sorensen et al. altogether fail to identify blood tests that are each for identifying low level activation of the coagulation response in blood, fail to specify performing such tests on a blood sample taken from a subject, and fail to specify if at least two of the different blood tests identify low level activation of the coagulation response in the blood sample are abnormal then using the at least two of the blood tests to assist in diagnosing the subject with one of the conditions that cause a low level activation of the coagulation response in blood. Accordingly, Sorensen et al. do not, and cannot, anticipate Appellants' claim 84.

Dependent claim 85

Claim 85 depends upon claim 84 that is allowable according to the argument set forth above and, therefore, is allowable.

Independent claim 86

Claim 86 specifies an ex vivo diagnostic method including identifying a condition that causes a low level activation of the coagulation response in blood; providing a blood sample taken from a subject; providing different blood tests that are each for identifying low level activation of the coagulation response in blood; the blood tests comprising tests for fibrinogen, prothrombin fragment 1+2, thrombin/antithrombin complexes, soluble fibrin monomer, and platelet activation; and if at least two of the results are abnormal, using the abnormal results to assist in diagnosing the subject with the condition.

As indicated above in connection with claim 70, Sorensen et al. altogether fail to identify blood tests that are each for identifying low level activation of the coagulation response in blood, fail to specify performing such tests on a blood sample taken from a subject, and fail to specify if at least two of the different blood tests identify low level activation of the coagulation response in the blood sample are abnormal then using

the at least two of the blood tests to assist in diagnosing the subject with one of the conditions that cause a low level activation of the coagulation response in blood. Accordingly, Sorensen et al. do not, and cannot, anticipate Appellants' claim 86.

Dependent claim 87

Claim 87 depends upon claim 86 that is allowable according to the argument set forth above and, therefore, is allowable.

**C.**

**Issue**: Whether claims 70-87 are patentable over Dati et al.

Claims 70-87 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Dati et al. Appellants respectfully traverse this rejection. The claims are presented in one group by the examiner, that group of claims now on appeal being claims 70-87. None of the claims necessarily stands or falls together. Accordingly, independent claims 70, 77, 84, and 86 are treated below individually, as are the corresponding claims depending from each of the independent claims.

Dati et al. disclose that pregnancy and puerperium are hypercoagulable states with increased incidence of thromboembolic events and hemostasis. The physiological or pathophysiological activation of hemostasis, e.g., the stoppage of bleeding, results in the generation of activation markers which increase, reflecting hypercoagulability and thus an imbalance in the hemostatic system. The activation markers as set forth in Data et al. include thrombin-antithrombin III complex (TAT), antithrombin III itself, prothrombin fragment 1+2 (F 1+2), fibrin monomer (soluble fibrin), and D-Dimer. These activation markers, as taught by Dati et al., are useful to predict and monitor the severity of the condition.

Independent claim 70

Claim 70 claims an ex vivo diagnostic method including identifying conditions that each cause a low level activation of the coagulation response in blood; providing a blood sample taken from a subject; providing different blood tests that are each for identifying low level activation of the coagulation response in blood; performing each of the different blood tests on the blood sample; and if at least two of the different blood tests identify low level activation of the coagulation response in the blood sample are abnormal, using the at least two of the

blood tests to assist in diagnosing the subject with one of the conditions.

Dati et al. are concerned with utilizing activation markers to predict and monitor hypercoagulable states in pregnancy and puerperium. In Appellants' claim 70, the method is not directed to utilizing activation markers to predict and monitor hypercoagulable states in pregnancy and puerperium. Quite to the contrary, Appellants' method set forth in claim 70 is concerned first with identifying conditions that each cause a low level activation of the coagulation response in blood, performing tests on the blood sample that are each for identifying low level activation of the coagulation response in blood, and if at least two of the different blood tests identify low level activation of the coagulation response in the blood sample are abnormal, using the at least two of the blood tests to assist in diagnosing the subject with one of the conditions. The ability to test a blood sample in order to determine whether the blood sample has low level activation of the coagulation response provides a way to assist in diagnosing the subject from which the sample was taken with a condition that causes a low level activation of the coagulation response.

As explained above, the procedure in Dati et al. is carried out on pregnant women and women just following childbirth, which are hypercoagulable states. Pregnancy and puerperium are not conditions that cause a low level activation of the coagulation response in blood as specified by Appellants in claim 70. By monitoring the activation markers according to Dati et al., the hypercoagulable states in pregnant women and women just following childbirth can be monitored and predicted. Clearly, the method in Dati et al. do not have all of the steps of the invention claimed in claim 70, and is for an entirely different purpose, the results of which are used to monitor and predict the severity of hypercoagulable states. Because the method in Dati et al. is for an entirely different purpose from the claimed invention set forth in claim 70 and obtains results that are entirely different from Appellants' invention set forth in claim 70, one having ordinary skill in the art in looking at Dati et al. would have no way of arriving at Appellants' claimed invention. Thus, any inherency argument must fail. Since Dati et al. do not disclose all of the steps of Appellants' method claimed in claim 70, Dati et al. cannot function as a section 102 reference against claim 70. Thus, Dati et al. do not anticipate claim 70, since each and every element as set forth

in the claim is not found, either expressly or inherently described, in Dati et al.

In sum, Dati et al. altogether fail to identify blood tests that are each for identifying low level activation of the coagulation response in blood, fail to specify performing such tests on a blood sample taken from a subject, and fail to specify if at least two of the different blood tests identify low level activation of the coagulation response in the blood sample are abnormal then using the at least two of the blood tests to assist in diagnosing the subject with one of the conditions that cause a low level activation of the coagulation response in blood. Accordingly, Dati et al. do not, and cannot, anticipate Appellants' claim 70.

Dependent claims 71-76

Claims 71-76 depend upon claim 70 that is allowable according to the argument set forth above and, therefore, are allowable.

Independent claim 77

Claim 77 specifies an ex vivo diagnostic method including identifying a condition that causes low level activation of the coagulation response in blood; providing a blood sample taken from a subject; providing different blood tests that are each for identifying low level activation of the coagulation response in blood; performing the different blood tests on the blood sample; and if at least two of the different blood tests identify low level activation of the coagulation response in the blood sample, using the at least two of the blood tests to assist in diagnosing the subject with the condition.

As indicated above in connection with claim 70, Dati et al. altogether fail to identify blood tests that are each for identifying low level activation of the coagulation response in blood, fail to specify performing such tests on a blood sample taken from a subject, and fail to specify if at least two of the different blood tests identify low level activation of the coagulation response in the blood sample are abnormal then using the at least two of the blood tests to assist in diagnosing the subject with one of the conditions that cause a low level activation of the coagulation response in blood. Accordingly, Dati et al. do not, and cannot, anticipate Appellants' claim 77.

Dependent claims 78-83

Claims 78-83 depend upon claim 77 that is allowable according to the argument set forth above and, therefore, are allowable.

Independent claim 84

Claim 84 specifies an ex vivo diagnostic method including identifying conditions that each cause a low level activation of the coagulation response in blood, providing a blood sample taken from a subject; providing different blood tests that are each for identifying low level activation of the coagulation response in blood; the blood tests comprising tests for at least two of fibrinogen, prothrombin fragment 1+2, thrombin/antithrombin complexes, soluble fibrin monomer, and platelet activation; obtaining a result for each of the blood tests; observing the results; and if at least two of the results are abnormal, using the abnormal results to assist in diagnosing the subject with one of the conditions.

As indicated above in connection with claim 70, Dati et al. altogether fail to identify blood tests that are each for identifying low level activation of the coagulation response in blood, fail to specify performing such tests on a blood sample

taken from a subject, and fail to specify if at least two of the different blood tests identify low level activation of the coagulation response in the blood sample are abnormal then using the at least two of the blood tests to assist in diagnosing the subject with one of the conditions that cause a low level activation of the coagulation response in blood. Accordingly, Dati et al. do not, and cannot, anticipate Appellants' claim 84.

Dependent claim 85

Claim 85 depends upon claim 84 that is allowable according to the argument set forth above and, therefore, is allowable.

Independent claim 86

Claim 86 specifies an ex vivo diagnostic method including identifying a condition that causes a low level activation of the coagulation response in blood; providing a blood sample taken from a subject; providing different blood tests that are each for identifying low level activation of the coagulation response in blood; the blood tests comprising tests for fibrinogen, prothrombin fragment 1+2, thrombin/antithrombin complexes, soluble fibrin monomer, and platelet activation; and if at least two of the results are abnormal, using the abnormal results to assist in diagnosing the subject with the condition.

As indicated above in connection with claim 70, Dati et al. altogether fail to identify blood tests that are each for identifying low level activation of the coagulation response in blood, fail to specify performing such tests on a blood sample taken from a subject, and fail to specify if at least two of the different blood tests identify low level activation of the coagulation response in the blood sample are abnormal then using the at least two of the blood tests to assist in diagnosing the subject with one of the conditions that cause a low level activation of the coagulation response in blood. Accordingly, Dati et al. do not, and cannot, anticipate Appellants' claim 86.

Dependent claim 87

Claim 87 depends upon claim 86 that is allowable according to the argument set forth above and, therefore, is allowable.

**D.**

**Issue**: Whether claims 77-83 are substantial duplicates of claims 70-76.

Claims 77-83 are deemed substantial duplicates of claims 70-76. Appellants traverse this rejection.

Independent claim 70 includes identifying conditions that each cause a low level activation of the coagulation response in blood, and if at least two of the different blood tests identify low level activation of the coagulation response in the blood sample are abnormal, using the at least two of the blood tests to assist in diagnosing the subject with one of the conditions. Unlike claim 70, claim 77 specifies identifying a condition that causes low level activation of the coagulation response in blood, and if at least two of the different blood tests identify low level activation of the coagulation response in the blood sample, using the at least two of the blood tests to assist in diagnosing the subject with the condition. Claim 70 is carried out in the environment of identifying conditions that cause a low level activation, and claim 77 is carried out in the environment where only one condition that causes a low level

activation of the coagulation response is required. Claims 70 and 77 are very similar, but are indeed different.

**E.**

**Issue**: Whether claim 84 is a substantial duplicate of claims 74 and 81.

Claim 84 is deemed a substantial duplicate of claims 74 and 81. Appellants traverse this rejection.

Claim 84 is an independent claim, and cannot be the substantial duplicate of dependent claim 74, which depends from claim 70, and dependent claim 81, which depends from claim 77.

**F.**

**Issue**: Whether claim 86 is a substantial duplicate of claims 76 and 83.

Claim 86 is deemed a substantial duplicate of claims 76 and 83. Appellants traverse this rejection.

Claim 86 is an independent claim, and cannot be the substantial duplicate of dependent claim 76, which depends from claim 70, and claim 83, which depends from claim 77.

**G.**

**Issue**: Whether claims 70-87 unpatentable over claims 45-63 of copending Application No. 10/915,018.

Claims 70-87 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 45-63 of copending Application No. 10/915,018. Appellants respectfully traverse this rejection.

Appellants note and respectfully traverse the provisional double patenting rejection on pages 6-7 of paper no. 20070426 as

the subject matter claimed in the present application is altogether different from the subject claimed in claims 45-63 of Appln. No. 10/915,018 given that as of the date of this Appeal Brief claim 45 has been significantly amended to relate specifically to a method for determining whether a blood sample has a hereditary propensity for hypercoagulability, and claims 46-63 are now canceled.

**VIII. Summary**

The claims on appeal are clear and unambiguous and are directed to the invention. Appellants discussion of the patentability of claims subject to this appeal over Wintrobe et al., Sorensen et al., and Dati et al. is also clear and unambiguous. As explained above, Wintrobe et al., Sorensen et al., and Dati et al. each have no application toward the claims subject to this appeal. Although on page 3 of paper no. 20070426 it is stated that it is unclear what limitation of the claimed invention Appellants' feel Wintrobe et al., Sorensen et al., and Dati et al. do not teach, Appellant has fully responded to the rejections of the claims according to the argument set forth above and in prior responses in this case and has clearly

identified the combination of claim limitations Wintrobe et al., Sorensen et al., and Dati et al. fail to teach. Appellants' respectfully submit, according to the argument set forth above, that the content of Wintrobe et al., Sorensen et al., and Dati et al. altogether fail to incorporate the subject matter claimed by Appellants in claims 70, 77, 84, 86, and the corresponding dependent claims, and that, therefore, Wintrobe et al., Sorensen et al., and Dati et al. are each not properly applied to the claims on appeal. Claims 70, 77, 84, and 86 are each appropriate in scope, directed to the invention, and clear and unambiguous, as is each of the corresponding dependent claims.

On page 4 of paper no. 20070426 it is stated that the claimed invention does not require additional treatment steps, thereby intimating that the claimed invention somehow would require treatment steps. Appellants do not understand this line of reasoning and desire to claim diagnostic methods as specified in the claims subject to this appeal.

Pursuant to the foregoing, Appellants believes that the rejections of claims 70-87 are supported by an entirely unsatisfactory and faulty analysis of the prior art and are quite incorrect, and that the rejections thereof and of the

corresponding dependent claims are moot and should be withdrawn. Accordingly, any rejection not specifically addressed is not to be construed as an admission that the position taken in paper no. 20070426 is correct or agreed upon, or that Appellants concedes the position set forth in paper no. 20070426. Quite the contrary, each and every rejection set forth in paper no. 20070426 is believed to be based on an entirely incorrect analysis of the prior art as explained herein and are respectfully traversed.

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Respectfully submitted,

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**CN 45848**

**CLAIMS APPENDIX A**

70. An ex vivo diagnostic method comprising steps of:

identifying conditions that each cause a low level activation of the coagulation response in blood;

providing a blood sample taken from a subject;

providing different blood tests that are each for identifying low level activation of the coagulation response in blood;

performing each of the different blood tests on the blood sample; and

if at least two of the different blood tests identify low level activation of the coagulation response in the blood sample are abnormal, using the at least two of the blood tests to assist in diagnosing the subject with one of the conditions.

71. The method of claim 70, further comprising the steps of providing a population of blood samples, and performing the method of claim 70 for each of the blood samples of the population.

72. The method of claim 70, wherein the different blood tests comprise tests for at least two of fibrinogen, prothrombin fragment 1+2, thrombin/antithrombin complexes, and soluble fibrin monomer.

73. The method of claim 70, wherein the different blood tests comprise tests for at least three of fibrinogen, prothrombin fragment 1+2, thrombin/antithrombin complexes, and soluble fibrin monomer.

74. The method of claim 70, wherein the different blood tests comprise tests for at least two of fibrinogen, prothrombin fragment 1+2, thrombin/antithrombin complexes, soluble fibrin monomer, and platelet activation.

75. The method of claim 70, wherein the different blood tests comprise tests for at least three of fibrinogen, prothrombin fragment 1+2, thrombin/antithrombin complexes, soluble fibrin monomer, and platelet activation.

76. The method of claim 70, wherein the different blood tests comprise tests for fibrinogen, prothrombin fragment 1+2, thrombin/antithrombin complexes, soluble fibrin monomer, and platelet activation.

77. An ex vivo diagnostic method comprising steps of:

identifying a condition that causes low level activation of the coagulation response in blood;

providing a blood sample taken from a subject;

providing different blood tests that are each for identifying low level activation of the coagulation response in blood;

performing the different blood tests on the blood sample; and

if at least two of the different blood tests identify low level activation of the coagulation response in the blood sample, using the at least two of the blood tests to assist in diagnosing the subject with the condition.

78. The method of claim 77, further comprising the steps of providing a population of blood samples and performing the method of claim 77 for each of the blood samples of the population.

79. The method of claim 77, wherein the different blood tests comprise tests for at least two of fibrinogen, prothrombin fragment 1+2, thrombin/antithrombin complexes, and soluble fibrin monomer.

80. The method of claim 77, wherein the different blood tests comprise tests for at least three of fibrinogen, prothrombin fragment 1+2, thrombin/antithrombin complexes, and soluble fibrin monomer.

81. The method of claim 77, wherein the different blood tests comprise tests for at least two of fibrinogen, prothrombin fragment 1+2, thrombin/antithrombin complexes, soluble fibrin monomer, and platelet activation.

82. The method of claim 77, wherein the different blood tests comprise tests for at least three of fibrinogen, prothrombin fragment 1+2, thrombin/antithrombin complexes, soluble fibrin monomer, and platelet activation.

83. The method of claim 77, wherein the different blood tests comprise tests for fibrinogen, prothrombin fragment 1+2, thrombin/antithrombin complexes, soluble fibrin monomer, and platelet activation.

84. An ex vivo diagnostic method comprising steps of:

identifying conditions that each cause a low level activation of the coagulation response in blood;

providing a blood sample taken from a subject;

providing different blood tests that are each for identifying low level activation of the coagulation response in blood;

the blood tests comprising tests for at least two of fibrinogen, prothrombin fragment 1+2, thrombin/antithrombin complexes, soluble fibrin monomer, and platelet activation;

obtaining a result for each of the blood tests; observing the results; and

if at least two of the results are abnormal, using the abnormal results to assist in diagnosing the subject with one of the conditions.

85. The method of claim 84, further comprising the steps of providing a population of blood samples, and performing the method of claim 84 for each of the blood samples of the population.

86. An ex vivo diagnostic method comprising steps of:

identifying a condition that causes a low level activation of the coagulation response in blood;

providing a blood sample taken from a subject;

providing different blood tests that are each for identifying low level activation of the coagulation response in blood;

the blood tests comprising tests for fibrinogen, prothrombin fragment 1+2, thrombin/antithrombin complexes, soluble fibrin monomer, and platelet activation; and

if at least two of the results are abnormal, using the abnormal results to assist in diagnosing the subject with the condition.

87. The method of claim 86, further comprising the steps of providing a population of blood samples, and performing the method of claim 86 for each of the blood samples of the population.

**EVIDENCE APPENDIX B**

There is no evidence submitted pursuant to 37 C.F.R. §§1.130, 1.131, or 1.132 or any other evidence entered and relied upon in this appeal.

**RELATED PROCEEDINGS APPENDIX C**

There are no copies of decisions rendered by a court or the Board in any proceeding because there are no other appeals, interferences, or judicial proceedings known to Appellants, the Appellants's legal representative, or assignee which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.